



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/501,344 | 01/26/2005 | Dominique Swinnen | 255452US0PCT | 6094 |
| 22850 | 7590 | 09/05/2008 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | |
| EXAMINER | | | | |
| MABRY, JOHN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1625 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 09/05/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary

Application No.

10/501,344

Applicant(s)

SWINNEN ET AL.

Examiner

John Mabry, PhD

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 12, 14, 27, 28 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 12, 14, 27, 28 and 42-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 6/11/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Examiner's Response

Applicant's response on June 11, 2008 filed in response to the Office Action dated January 11, 2008 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

Status of the Claims

Claims 42-47 are new.

Claims 1, 5, 12, 14, 27, 28 and 42-47 are pending and rejected.

Claims 2-4, 6-11, 13, 15-26 and 29-41 have been cancelled.

35 USC § 112 Rejection(s)

The 112-2nd rejection of claims 1, 5, 12, 27, 28 and 42-45 regarding the term "derivatives" in particular the term pharmaceutical active derivatives, still persists in claim 1 have not been overcome in view of Applicants amending the claims.

The 112-2nd rejection of claims 28 and 29 regarding use of trademarks has been overcome in view of Applicants cancelling and amending the claims.

The 112-1st rejection of claims 29 regarding the phrase

acting insulin, an intermediate acting insulin, a long acting insulin, a combination of intermediate and rapid acting insulins,

as unduly functional has been overcome in view of Applicants amendment.

The 112-1st rejection of claims 1-18 and 27-29 regarding the scope of enablement for the substitution of "Cy and A" have been overcome in view of Applicants amending and cancelling claims.

35 USC § 102(e) Rejection(s)

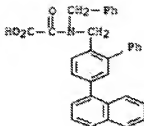
Applicant's arguments with respect to 102(e) rejections have been fully considered and are persuasive. The 102(e) rejection of claims 1-4, 9, 12-14 and 27-29 regarding anticipation by Liu et al (US 6,627,767 B2) has been withdrawn.

35 USC § 103(a) Rejection(s)

Applicant's arguments with respect to 103(a) rejections have been fully considered and are persuasive. The 103(a) rejection of claims 1-3 regarding obviousness over Burrows et al (J. Org. Chem. 1982, 47, 892-893) has been withdrawn.

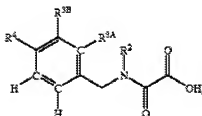
Applicant's arguments with respect to 103(a) rejections have been fully considered and are not persuasive. The 103(a) rejection of claims 1-5, 9-18 and 27-29 (currently claims 1, 5, 12, 14, 27-28 and 42-47 regarding obviousness over Liu et al (US 6,627,767 B2) stands rejected.

As stated in Non-Final Office Action, Liu discloses compounds of Formula I where R1=CH2Ph, R2a and R2b=H, Cy=phenyl substituted with phenyl and naphthyl (see Example 30, column 31, lines 5—60, compound below).



Also detailed in Non-Final Office Action was that Lui describes a genus teaching in which compounds of Formula I where Cy=phenyl which is substituted phenyl. This is a clear suggestion that this compound is not required to be substituted by a naphthyl group. Lui et al still teaches the genus as claimed by instant application (see Formula III, column 3, top left column and entire document).

(III)



or therapeutically acceptable salts thereof, wherein R^2 and R^4 are defined previously; R^{3A} is selected from hydrogen, loweralkoxy, alkoxycarbonylalkenyl, alkoxycarbonylalkoxy, aryl, carboxamidoalkenyl, carboxamidoalkoxy, carboxyalkenyl, carboxyalkoxy, halo, and heteroarylalkoxy; and R^{3B} is selected from hydrogen and halo.

According to Lui, the phenyl group can substituted by many chemical groups (see column 7, lines 16-39) and R^2 =phenyl (see column 2, lines 1-3).

An action on the merits of claims 1 is contained herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. R1 is CH-phenyl or CH-naphthyl. The CH- portion would not fulfill the correct valency for carbon, which is four and would not have a complete octet. Applicant only describes a three-bonded carbon. This rejection is necessitated by Applicant's amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention – new matter. Claim 1 has been amended to read "CH-phenyl, CH-naphthyl". This rejection is necessitated by Applicant's amendment

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625